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Registration Decision RD2017-10

Polyoxin D zinc salt

(publié aussi en français)

1 June 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2017-10E (print version)
H113-25/2017-10E-PDF (PDF version)

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Registration Decision Statement[1] for Polyoxin D Zinc Salt

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Polyoxin D Zinc Salt Technical and its associated end-use products: Polyoxin D Zinc Salt 5SC Fungicide, Polyoxin D Zinc Salt 11.3% WDG Fungicide, Polyoxin D Zinc Salt 11.3% WDG Domestic Fungicide, containing the technical grade active ingredient polyoxin D zinc salt, to suppress or control a broad range of diseases in various crops grown outdoors or under greenhouse conditions.

This decision is consistent with the Proposed Registration Decision PRD2017-03, *Polyoxin D zinc salt*, which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-03, *Polyoxin D zinc salt*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. **Comment**
On Page 21, §7.1, paragraph 2. "In vitro micronucleus test" should be "in vivo micronucleus test."

Response
The PMRA agrees that this was a typographical error.

2. **Comment**
The 1 m buffer zone is not necessary and the buffer zone requirement should be deleted from the product labels. Polyoxin D zinc salt is registered for use in the United States, Mexico, New Zealand and many countries in Asia. No other regulatory authority has required a buffer zone for application of polyoxin D zinc salt products. The PRD states, "The screening level risk quotient for acute exposure of amphibians to polyoxin D zinc salt marginally exceeded the LOC (RQ=1.2)." Screening level risk assessments do not consider risk reduction factors. For example, polyoxin D degrades readily in the environment via hydrolysis and aqueous photolysis. Amphibians will be adequately protected in the absence of a 1m buffer zone.

Response
Upon completion of the screening level environmental risk assessment for Polyoxin D zinc salt technical and its formulations, it was determined that the level of concern (LOC = 1) for one group of organisms, amphibians, was slightly exceeded (RQ = 1.2). Although no risk was identified with further refinements of the risk assessment, it is standard procedure for the PMRA to apply a 1 m buffer zone as a risk mitigation measure. Hydrolysis of polyoxin D (25 °C, pH 7.0) occurs with a half-life of 32.5 days. However, polyoxin D undergoes relatively rapid aquatic phototransformation with a half-life of 2.4 days (pH 7). Phototransformation of polyoxin D in shallow bodies of water could mitigate the exposure of amphibians in these habitats. Based on the fact that the LOC was only marginally exceeded and that there are some conservatisms in the risk assessment for estimating exposure to amphibians (for example, full application rate with no transformation), the PMRA agrees that the 1 m buffer zone is not required and it has been removed from the label.